

## **RESPONSE**

Claims 1, 13-15, 18 and 22 are pending in the application.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 1, 13-15, 18 and 22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of U.S. Patents 5,545,628 ('628) and 4,769,236 ('236). The rejection is respectfully traversed for the reasons set forth herein and in Applicants' January 25, 2006 response.

It is well established law that the PTO has the burden under 35 U.S.C. §103 to establish a case of *prima facie* obviousness (*In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988)). To satisfy this burden, an Examiner must identify both (i) a suggestion to modify a primary reference in accordance with the teachings of one or more secondary references to achieve the claimed invention and (ii) a reasonable expectation of success in making and using the modified procedure (*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)). Furthermore, both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure (*In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988)). The modification must be more than just "obvious to try", which the Court of Appeals for the Federal Circuit has rejected as a standard for obviousness (*In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988)). Moreover, in combining references, the Examiner may not use an applicant's disclosure as a guide or template to select elements or features from among prior art references which, when assembled together, arrive at the claimed invention (*In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992)). Under these standards, Applicants respectfully contend that the combined teachings of '628 and '236, fail to render Applicant's invention obvious.

The teachings of '236 are directed to a solid dispersion of a product in its amorphous form by spraying in the presence of polyvinylpyrrolidone (PVP), alone or in combination with polyethyleneglycol (PEG) as a stabilizer. The teachings of '236 fail to describe the use of hydroxypropylmethylcellulose (HPMC), or fenofibrate as part of the solid dispersion.

The teachings of '628 are directed to a composition of fenofibrate prepared by melting PEG, fenofibrate and HPC (optionally as a stabilizer). The final composition is

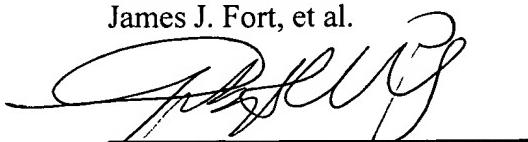
liquid and capsules are filled with this liquid composition using a liquid filling capsule machine (Col. 4). Therefore, fenofibrate is never in solid state in the composition described in '625.

The Office Action stated that it would have been obvious to one of skill in the art to prepare a fenofibrate composition based on the combinations of the teachings of '625 and '236. Applicants respectfully disagree as being a mere speculation laced with forbidden hindsight.

Applicants submit that '628 fails to provide the motivation or suggestion to use a solid dispersion rather than the liquid melted to make a composition of fenofibrate. Similarly, '628 fails to describe the desirability to spray-dry the melted solution as taught in '236 or, to subject the melted solution to rapid evaporation as taught in the present application using HPMC. Applicants also submit that '236 did not choose to make the solid dispersion for fenofibrate, and additionally, did not chose to make the amorphous solid dispersion of fenofibrate by spraying in the presence of a stabilizer, which in the case of '236 is PVP. Applicants submit that the teachings of '625 and '236 combined not only fail to provide any motivation or suggestion of using a solid dispersion of fenofibrate using HPMC, but also, that one of ordinary skill in the art would not have a reasonable expectation of success when using a combination of the teachings of '625 and '236 to make the solid dispersion of fenofibrate of the present invention.

In view of the foregoing remarks, Applicants submit that the Office Action has failed to present a *prima facie* case of obviousness. Applicants respectfully request favorable reconsideration of claims 1, 13-15, 18 and 22 and allowance of this application.

Respectfully submitted,  
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